IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**Case No. 1:22-cv-00071** **MDL 3026** **Hon. Rebecca R. Pallmeyer**
This Document Relates to: **ALL CASES**	

DEFENDANTS' JOINT MOTION TO EXCLUDE DR. LOGAN SPECTOR

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INTRODUCTION

Dr. Logan Spector's causation opinion suffers from an array of fundamental flaws, each of which is independently fatal to the admissibility of his testimony under Rule 702. After applying a made-for-court methodology that he ***admits*** is less rigorous and different from what he would do in a scientific context, Dr. Spector then proceeded to offer an opinion that has ***no relevance*** to any identified case in this MDL—and certainly no relevance to any of the bellwether cases. And he offered all of this in a scientific context where, before being hired by Plaintiffs, his study of NEC was limited to citing a single paper whose title contained the word "NEC" in an article he wrote about pediatric cancer more than a decade ago. Rule 702 requires his exclusion.

Most fundamentally, Dr. Spector followed a made-for-litigation methodology that, contrary to Rule 702's requirements, openly differs from what he concedes would be necessary in a scientific context. Indeed, Dr. Spector *conceded* that he departed from his ordinary methodology because his work here was "solely for court purposes." *E.g.*, Ex. 7, Spector Dep. Tr. 12/23/2024 at 222:13–223:14. And he further acknowledged that his causation opinion itself would be different in a scientific context, saying "I don't know" whether outside of litigation he would say there was more than "a possibility that preterm formula causes NEC." *Id.* at 201:6–14. An expert opinion that employs a lower level of "'intellectual rigor'" than would ordinarily be applied in the relevant field is necessarily inadmissible. *See In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d 793, 818 (S.D. Ill. 2024) (quoting *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Next, his opinion should be excluded on "fit" grounds because he has no opinion relevant to *any* of the bellwether cases before the Court, or to the overwhelming majority of cases in this MDL. Dr. Spector admitted that his causation opinion applies only in instances where an infant born under 1500 grams received 100% cow's milk formula, with no measure of human milk. Doctors attempt to feed almost every preterm infant—and especially those under 1500 grams—

human milk where it is available. Defendants are unaware of any case in this MDL meeting Dr. Spector's outlier criteria. Certainly, none of the bellwether cases involve these circumstances. He thus has nothing to offer the jury on general causation in any case identified to the Court.

Finally, as the above issues reflect, Dr. Spector is not qualified to give his opinions. Dr. Spector's research outside this litigation does not focus on neonatal nutrition, he has never studied NEC or analyzed the causes of NEC other than as a paid expert for this MDL, and he did not do the work necessary to overcome that lack of knowledge.

For each of these reasons, Dr. Spector's opinions should be excluded in their entirety.

BACKGROUND

Premature infants face a host of complications because they are born before their bodies are ready for the outside world: their blood cannot adequately carry oxygen; they often have heart complications, trouble breathing, and trouble seeing; and they face a higher risk of brain hemorrhages. They also face a higher risk of NEC, a serious gastrointestinal disease that almost exclusively affects preterm infants. Indeed, the medical community recognizes prematurity as the "most prominent [NEC] risk factor," Ex. 10, Singh et al., *Necrotizing Enterocolitis: Bench to Bedside Approaches and Advancing our Understanding of Disease Pathogenesis*, Frontiers in Pediatrics (2023), at 2, and that "the best way to prevent NEC is the prevention of preterm birth." Ex. 2, *Report to Sec'y, Dep't of Health and Hum. Srvs.* at iv (Sept. 16, 2024). For these reasons, preterm infants typically spend weeks, if not months, receiving around-the-clock medical care in a neonatal intensive care unit ("NICU") before their parents can take them home.

Nutrition and growth are perhaps the most critical components of caring for these infants. The medical community universally recognizes that mother's own milk (often when combined with a cows-milk derived fortifier) is the first choice for preterm infant nutrition due to its many protective properties. *See* Ex. 11, Am. Academy of Pediatrics, *Necrotizing Enterocolitis*

Overview, AAP.org (last updated July 17, 2024). Where mother's own milk is not available in sufficient supply, donor milk is frequently the next choice. *Id.* Preterm formula is used as the "standard of care" when donor milk is unavailable, or when doing so is medically or nutritionally necessary. Ex. 1, FDA, CDC, NIH, *Consensus Statement on Recent Advisory Council Report on Premature Infants and Necrotizing Enterocolitis* (Oct. 3, 2024) ("Consensus Statement"). The medical community endorses the use of preterm formula as "a routine and necessary part of care of these preterm infants." Ex. 6, Am. Acad. of Pediatrics, *Statement in Response to NEC Lawsuit Verdicts*, AAP.org (July 27, 2024) ("AAP Statement").

For decades, various studies have evaluated NEC rates in preterm infants fed human milk versus cow's-milk formula. Some of these studies show that feeding preterm infants human milk, and particularly mother's own milk, lowers the risk of NEC. For this reason, the agreed-on view of the medical community is that (1) human milk has protective qualities that reduce the risk of NEC, but which preterm formulas cannot replicate, (2) and "[t[here is no conclusive evidence that preterm infant formula causes NEC." Ex. 1, Consensus Statement. *See also, e.g.*, Ex. 3, Lucas & Cole, *Breast Milk and Neonatal Necrotising Enterocolitis*, 336 The Lancet 1519, 1521 (1990); Ex. 2 at 10, 48–49; Ex. 4, Am. Acad. of Pediatrics, *Breastfeeding and the Use of Human Milk*, Pediatrics, Mar. 2012 ("AAP 2012"); Ex. 5, Am. Acad. of Pediatrics, *Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States*, Pediatrics, Jan. 2017 ("AAP 2017").

Plaintiffs proffered Dr. Spector to disagree with the medical consensus even though he has never grappled with this issue before being hired in these cases. His research focuses on pediatric cancers. Ex. 7 at 315:12–21 He has never analyzed the causes of NEC other than as a paid expert for this MDL. *Id.* at 114:25–115:1. Dr. Spector's purported methodological basis for reaching

this contrary conclusion was (1) he claimed that he conducted a "systematic literature review" ("SLR") of the full study data and documented that review using a method referred to as the PRISMA methodology, *id.* at 362:18–25; (2) he had another expert (Dr. Rebecca Betensky) perform various meta-analyses[1] of specific studies he found through that SLR; and (3) after adopting the meta-analyses, he then purported to conduct a Bradford Hill evaluation—an analysis of nine criteria used by epidemiologist to assess causation. Every step of this methodology was unreliable: (1) he failed to actually conduct a systematic review of the literature, deviating from the PRISMA methodology; (2) he admitted he could not conclude causation from Dr. Betensky's meta-analyses alone, which in any event contained a host of admitted errors, including an "egregious" one that he declined to fix, Ex. 20, Spector Suppl. Dep. Tr. 1/31/2025 at 118:13–22; and (3) his Bradford Hill analysis consisted of nothing beyond Dr. Betensky's meta-analyses. Finally, he admitted that he could offer only the narrowest opinion—that cow's milk formula, but not fortifier, causes NEC only in babies under 1500 grams who receive a 100% cow's-milk diet, with him unable to render any opinion relating to infants fed any lesser amount.

Weeks after Defendants deposed him on these defects, and months after the deadline for rebuttal reports had passed, Dr. Spector served an amended version of his report that purported to fix some, but not all, of his admitted errors. He also served an entirely new expert report with eight new analyses that magnified the made-for-litigation nature of his opinions: he admitted that they were merely "ad hoc" responses to study omissions that he learned about at his deposition.

[1] A meta-analysis attempts to combine data across studies to generate a single result for the full dataset. Ex. 19, Reference Manual on Scientific Evidence: Third Edition 624, The National Academies Press (2011) ("*Reference Manual*"). Both in his original report and in his updated report, Dr. Spector reported the results of various meta-analyses he had Dr. Betensky perform for him, based on different study permutations, which unsurprisingly led to varying estimates of risk. *See* Ex. 8 at 15–16; Ex. 21, Spector Suppl. Rep. at 9–13.

LEGAL STANDARD

Rule 702 requires the party proffering an expert to show that (1) the expert is qualified; (2) the testimony "reflects a reliable application of the principles and methods to the facts of the case"; and (3) the testimony is relevant and helpful to the trier of fact. Fed. R. Evid. 702; *see also Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017) (same). Failure to meet any of these prongs requires exclusion. Fed. R. Evid. 702; *see also Cage v. City of Chicago*, 979 F.Supp.2d 787, 808 (N.D. Ill. 2013) ("[*A*]*ny step* that renders the analysis unreliable … renders the expert's testimony inadmissible.") (citation omitted, emphasis added).

In 2023, the Advisory Committee amended Rule 702 in two ways. *First*, to clarify that the criteria in Rule 702—qualifications, reliability, and helpfulness—are "critical questions" of *admissibility* rather than weight. Adv. Comm. Notes (2023) (proponent must demonstrate that each of Rule 702 factors are met by a preponderance of the evidence). *Second*, to "emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." *Id.* "Judicial gatekeeping" on these points is "essential" because jurors may lack the ability to determine both whether the methodology itself is reliable and whether the expert has improperly extrapolated beyond what the methodology supports. *Id.*

ARGUMENT

I. Dr. Spector's Methodology Is Unreliable and Litigation-Driven.

Dr. Spector admitted that he would never address NEC and formula outside of court given his lack of experience in the area: "I don't publish on disease states that I don't know about already." Ex. 7 at 356:15–16. He then conceded that to reach an opinion about NEC that he could offer in court, he used a less rigorous made-for-litigation methodology that he would not use outside of court. Rule 702 prohibits this type of litigation-driven methodology by ensuring that

"scientists testify[ing] in court … adhere to the same standards of intellectual rigor that are demanded in their professional work." *Rains v. PPG Indus., Inc.*, 361 F. Supp.2d 829, 832 (S.D. Ill. 2004) (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996)). Dr. Spector plainly ran afoul of this prohibition.

Dr. Spector's methodological shortcomings resulted in him: (1) applying a methodology he would not follow outside of court to reach an opinion he would never issue in his academic work; (2) failing to reliably apply standard epidemiological criteria to determine causation, which meant that he could not rule out alternative explanations for the data; and (3) violating basic standards for a reliable methodology. Any one of these "evidentiary red flag[s]" justifies his exclusion. *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d 793, 850 (S.D. Ill. 2024) (collecting cases).

A. Dr. Spector's Litigation Methodology Lacks the Rigor of His Academic Work.

By Dr. Spector's own admission, his methodology here was different and less rigorous from the one he would apply outside court. ***First***, he did not rigorously analyze the literature—that is, perform the "systematic literature review" that he claims is his methodology here—as he would outside court. When publishing systematic literature reviews outside of litigation, Dr. Spector dedicates "hours and hours of deliberation" and "agonize[s] over every word" of the manuscript and analysis. Ex. 7 at 201:10–14. This "agony process" involves fully reviewing the literature, ruling out potential alternative explanations for study findings, and analyzing the studies ultimately included in a meta-analysis. *See id.* at 197:23–198:5, 202:8–12.

He did none of that here. Far from "agoniz[ing] over every word," he admitted that he "did not read the [study] discussions in depth." *Id.* at 132:22–25. That is no surprise, as his review involved him spending approximately ***thirty seconds*** with each study. *Id.* at 260:14–21. This cursory review led him to dismiss thousands of studies as "irrelevant" even though they addressed

the precise question relevant to his analysis: NEC rates with formula. *E.g.*, *id.* at 25:23–26:1; Ex. 17, Spector: Irrelevant Studies (listing more than 5000 publications, including publications on formula and NEC, that Dr. Spector deemed "irrelevant" based on "skimming" them). Some of those papers were studies he admitted he would have likely included had he actually conducted a *systematic* literature review rather than litigation-driven literature "skimming." *E.g.*, Ex. 7 at 250:15–20.

After Dr. Spector was shown some of these studies during his deposition, he served a new, months-late "supplemental" report. This second report is late and hardly "supplemental," and it should be stricken. *See Malibu Media LLC v. Doe*, 2016 WL464045, at *13 (N.D. Ill. Feb 8, 2016) (supplementation exists only to permit a party to "correct inadvertent errors or omissions") (quotation omitted); *Solaia Tech. LLC v. ArvinMeritor, Inc.*, 361 F.Supp.2d 797, 806 (N.D. Ill. 2005) (noting that an expert's report was "prompted solely by [defendant]'s summary judgment motion. … This is not the proper role for supplementation of a report by an expert."); *Haller v. AstraZeneca Pharms. LP*, 598 F.Supp.2d 1271, 1296 (M.D. Fla. 2009) (excluding expert whose opinions were impacted by defendants' motion practice); *Gallagher v. Southern Source Packaging, LLC*, 568 F.Supp.2d 624, 630 (E.D.N.C. 2008) (collecting cases). Nevertheless, given that it is now before the Court, its flaws serve only to magnify the made-for-litigation nature of Dr. Spector's methodology. While Dr. Spector's supplemental report purported to address the studies he missed, he admitted that it was only "an ad hoc report," Ex. 20 at 18:17–19, he said that its accuracy was important to him only "[t]o some extent," *id.* at 19:18–20, and he suggested that he did not even actually read the studies discussed in his new report, as opposed to simply copying data about them from defense reports, *id.* at 156:6–14 ("Did you go and seek to derive those

numbers independently from what the defendants had reported in their expert reports? … A. I sought to use the numbers that were used by the defendants' experts.") (objection omitted).

His slapdash review similarly led him to make a series of admitted "misstatements" and "errors" in his report that flowed from his failure to apply his out-of-court standards of care to his litigation work. Ex. 20 at 12:10–16. He later attempted to correct some of these errors, in an amended report that he helpfully redlined for the Court, Ex. 8, Spector Am. Rep., but even then he left uncorrected his failure to notice that one of his key clinical trials counted a case of NEC from formula even though the formula was given only ***after*** the infant had NEC and recovered—an error he conceded was "egregious" Ex. 7 at 317:14–20.

Second, Dr. Spector admitted that he deviated from his out-of-court methods for reporting the results of his systematic literature review. He purported to apply the PRISMA methodology for reporting his work, only to admit that he deviated from it for his litigation work. PRISMA, for example, gives a specific checklist for writing an abstract. Ex. 22, PRISMA 2020 for Abstracts Checklist. But Dr. Spector "did not feel it was important to follow that abstract guideline to the T." Ex. 7 at 205:8–23. PRISMA requires a discussion of the "implications of the results [of the work] for practice, policy, and future research." Ex. 23, Spector PRISMA 2020 Checklist, at 48. But Dr. Spector admitted he did not follow this part of the methodology because his work was "solely for court purposes," with no implications outside Court. Ex. 7 at 222:13–223:14. This itself is a remarkable concession: If a scientist actually disproved the consensus view that formula does not cause NEC, such work would, of course, have implications for medicine and science. *See* Ex. 6, AAP Statement ("Special formulas designed for preterm infants provide an essential source of nutrition" and are "a routine and necessary part of care of these preterm infants."). Finally, he did not frame his review, as required, in terms of prior research because that would only be

necessary if he were "publishing in [] scientific literature" while his work here—testifying as a paid expert—had "an entirely different purpose." *Id.* at 227:10–228:3. And he omitted other PRISMA steps, such as actually assessing potential bias in the studies in a meaningful way. *Id.* at 217:11–218:12.

Third, as detailed further below, *see* Part I.C., Dr. Spector missed a host of studies in his first report, admitted that when he served his second report, and then admitted to missing still more when he was deposed regarding his second report. Again, that falls outside the standards he claims to follow in his scientific practice.

Most remarkably, Dr. Spector admitted that, had he followed his ***out-of-court*** methodology, his opinions would have been different. Using his litigation-driven methodology, Dr. Spector claimed "to a reasonable degree of scientific certainty that feeding preterm infants [preterm formula] causes NEC compared to feeding [human milk]." Ex. 8 at 26. He, of course, had to give such an opinion to support Plaintiffs' cases. Ex. 7 at 225:20–22 ("I assume that they would not put forth someone who does[] not help their case.").

But outside of Court, using a scientific methodology, he would not reach this litigation-driven opinion:

> **Q.** Okay. Would you frame your conclusion, if you were submitting this for peer review, as you did here, that you conclude to a reasonable degree of scientific certainty that feeding preterm infants causes NEC?
>
> . . .
>
> **A.** Scientists don't generally make statements like that in academic papers.

Ex. 7 at 198:6–14 (objection omitted). He could not say how he would phrase his opinion outside Court—"I don't know," *id.* at 198:16–18—but he could not even affirm that he would "use the word 'cause'" outside Court:

> I would perhaps have some sort of hedging language which, again, is what academics and scientists like to use because nobody likes to make a definitive statement that later will be proven wrong. However, there is a very different standard and expectation for how people describe results in the court's context.

Id. at 198:19–199:2. When pressed on whether he would recognize anything more than a "possibility" of causation outside of court, he admitted "I don't know."

> Q. Do you know if you would state anything stronger than there is a possibility that preterm formula causes NEC?
>
> …
>
> A. ***I don't know.*** When I write papers, it's like giving up a little part of your soul. It takes hours and hours of deliberation. And you agonize over every word.

Id. at 201:6–14 (emphasis added and objection omitted). An opinion about a mere possibility is insufficient to establish general causation. *See McCarty v. Menards*, 327 F.R.D. 177, 187 (N.D. Ill. 2018) ("The law does not recognize mere possibilities as a basis for liability."). And an expert who could not affirm that he would reach his more definitive litigation opinion outside of court because he had not undertaken the "hours and hours of deliberation" that an actual scientific opinion would require has admitted that his litigation methodology is not reliable.

In short, the simple fact that Dr. Spector used an admittedly watered-down methodology to reach opinions he would not offer outside court requires his exclusion. *See United States E.E.O.C. v. Rockwell Int'l Corp.*, 60 F.Supp.2d 791, 798 (N.D. Ill. 1999) (excluding expert because his "own admissions demonstrate that he failed to employ the same level of intellectual rigor that characterizes the practice of experts in his field, or even his own normal practice"); *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d at 818 ("Before an expert is permitted to testify, it is the Court's duty to ensure she 'employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'") (quoting *Kumho Tire Co. Ltd. v. Carmichael*, 526

U.S. 137, 152 (1999)); *Series 17-03-615 v. Express Scripts, Inc.*, 2024 WL 1834311, at *4 (N.D. Ill. Apr. 26, 2024) (excluding expert whose methodology lacked rigor).

B. Dr. Spector Did Not Properly Apply Bradford Hill and Could Not Otherwise Rule Out Alternative Explanations for the Data

Dr. Spector agreed that, just because "you see a statistically significant finding in a meta-analysis[,] that by itself does not mean we know causation exists." Ex. 20 at 31:17–21. This, of course, is a basic principle of science. As the *Reference Manual* recognizes: "epidemiology cannot prove causation; rather, causation is a judgment for epidemiologists and others interpreting the epidemiologic data." Ex. 19, *Reference Manual* at 598.

Epidemiologists often exercise that judgment by applying nine, established criteria referred to as the Bradford Hill criteria. *See id.* at 598–600 (listing criteria). These criteria are designed to rule out "alternative explanations for the association, such as bias or confounding factors." *Id.* at 598; *see also* Ex. 7 at 271:21–24. "Generally, researchers are conservative when it comes to assessing causal relationships, often calling for stronger evidence and more research before a conclusion of causation is drawn." Ex. 19, *Reference Manual* at 599. Dr. Spector purported to apply these criteria, but did so in a profoundly unreliable manner, and he admitted that he could not rule out alternative explanations for his conclusions.

1. Dr. Spector Did Not Reliably Apply the Bradford Hill Criteria.

Dr. Spector made no real effort to consider, let alone weigh, the nine Bradford Hill factors: strength of association; consistency; specificity; temporality; biologic gradient; experiment; plausibility; coherency; and analogy. He admitted he never meaningly considered four of them; conceded that three do ***not*** support a causal link between preterm formula and NEC; and for the remaining two, relied solely on Dr. Betensky's meta-analyses, which even he admitted *cannot*, standing alone, establish causation.

Specifically, Dr. Spector did not even meaningfully analyze more than a third of the Bradford Hill factors. For the biological plausibility, coherence, and analogy[2] factors, he did not actually consider evidence directly relevant to these factors but instead claimed to rely "on common sense, my generalist background in pediatric health, and the other experts' reports." Ex. 8 at 25. The first two *ipse dixit* claims are of course no basis for reliable expert testimony on a complex medical issue. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The third claim fares no better as his reliance on "other experts' reports" consisted of simply deferring to plaintiffs' mechanism expert's (Dr. Jennifer Sucre) work based on a misimpression that she had researched and published on the topic of NEC. Ex. 7 at 118:3–13. In fact, she has never done so. Ex. 9, Sucre Dep. Tr. 12/20/2024 at 19:13–20:7. In his academic work, Dr. Spector would not have relied on her without first accrediting her work. Ex. 7 at 356:17–22 ("Q. . . . If you wanted to have someone help you on the mechanistic side of an analysis, would you normally seek out someone who has published on that disease state before? A. Yes."). Simply parroting another expert, especially one whose work he was unfamiliar with, as he did with Dr. Sucre, is no basis for reliable expert testimony. *In re James Wilson Assocs.*, 965 F.2d 160, 173 (7th Cir. 1992); *Saginaw Chippewa Indian Tribe of Mich. v. Blue Cross Blue Shield of Mich.*, --- F. Supp. 3d ---, 2024 WL3813734, at *7 (E.D. Mich. Aug. 14, 2024) (collecting cases).

And as to the temporality factor, Dr. Spector only assumed it existed, writing that it "stands to reason that the [bovine-based nutrition product] was recorded with the correct temporality." Ex.

[2] Biological plausibility, in his words, evaluates whether the agent "could cause a disease on a biological level." Ex. 8 at 24. Coherence evaluates whether the "totality of the evidence," including non-study evidence, suggests causation, *id.*, with the *Reference Manual* providing as an illustration the fact that lung cancer rates increased with smoking rates, Ex. 19, *Reference Manual* at 606, an analysis Dr. Spector did not attempt here with formula use and NEC rates, *see* Ex. 7 at 307:13–16. Analogy involves comparing the association being evaluated to a "known, causal one," such as whether there is a so-called class effect. Ex. 8 at 24.

8 at 22. But even that "stands-to-reason" claim was wrong as to at least one study that he did not take the time to actually read. Ex. 7 at 178:22–179:12; 317:14–23 ("[I]t was sort of egregiously wrong[.]").

Regarding another third of the Bradford Hill factors, Dr. Spector conceded that they do not support causation. He admitted that he saw no data supporting the "experiment" factor—whether "cessation of exposure to th[e] agent . . . reduce[s] the risk of the disease," Ex. 19, *Reference Manual* at 605; Ex. 7 at 307:1–2. As to specificity—whether the agent is associated with a single outcome—Dr. Spector readily admitted that it "is considered a strong indicator of causality" that "***was not***" met here. *Id.* at 291:7–10; 291:5–6 ("**Q.** Okay. Did you find specificity met? **A.** There was not."). He gave no meaningful explanation for why that did not impact his opinion.

As to dose response—whether increasing the exposure to an agent increases the risk of an adverse outcome—Dr. Spector admitted that he undertook no quantitative dose-response analysis. Ex. 7 at 292:1–7. And he admitted that his "qualitative" consideration of this factor "did not show a clear dose response," including because the studies produced mixed results. *Id.* at 300:21–22; Ex. 8 at 23. When asked whether he could state "to a reasonable degree of scientific certainty based on the data you have seen in the studies that they show a dose response," he admitted that "the literature is insufficient to conclude that—or to quantify dose response." *Id.* at 301:16–25. All he could offer was unreliable musings: "there are emanations of a penumbra that suggest that there is a dose response." *Id.* at 301:21–25. When an expert is unable to claim dose response, that is an especially forceful basis for excluding his causation opinion. *See Newman v. Motorola, Inc.*, 78 Fed. App'x 292, 294 (4th Cir. 2003) (dose response is "an important factor in establishing causation"); *Pinares v. Raytheon Techs. Corp.*, 2023 WL 2661521, at *5 (11th Cir. Mar. 28, 2023)

(affirming exclusion of experts because they lacked "a dose-response assessment to establish general causation").

The only time Dr. Spector invoked actual evidence was to claim that a small minority—two of the nine—Bradford Hill factors were satisfied: strength of the association and consistency. And the only evidence he invoked as to these two factors were Dr. Betensky's meta-analyses,[3] which he acknowledged were insufficient alone to show causation. Ex. 20 at 31:17–21.

Moreover, his analysis of these two factors was itself methodologically unreliable. *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d at 840–41 (noting that experts must rigorously apply Bradford Hill) (citing *In re Mirena*, 341 F.Supp.3d 213, 247 (S.D.N.Y. 2018)). For the strength of association factor, Dr. Spector claimed that the relatively modest effect sizes in Dr. Betensky's meta-analyses were "consistent with generally accepted epidemiological standards to be strong," Ex. 8 at 21, even though he admitted at deposition that this claim was "context dependent" and that he could not cite anything in this context supporting the point that the meta-analysis findings were large enough to be strong. *See* Ex. 7 at 275:17–22, 282:15–17 ("Q. Okay. Can you point me to anything in the NEC context that recognizes that as strong? A. No.").

In terms of the consistency factor, instead of doing his own analysis, Dr. Spector justified his claim that the studies showed a consistent result by saying that he "eyeballed" them. *Id.* at 235:7–8. The studies themselves show the obvious unreliability of his subjective "eyeballing," as a quarter of them showed numerically ***lower*** rates of NEC with formula than human milk, *id.* at 236:22–237:12, and nine showed no statistically significant results. *Id.* at 238:1–3.

Courts routinely exclude experts who unreliably purport to find that all or nearly all the Bradford Hill criteria are satisfied. *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d at 841; *In*

[3] Ex. 7 at 193:5–7 (strength); 193:8–10 (consistency).

re Onglyza, 93 F.4th at 347–48; *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, 707 F.Supp.3d 309, 354 (S.D.N.Y. 2023). Dr. Spector's analysis falls far short of even those excluded experts, having no evidence to satisfy more than three-quarters of the criteria and relying on slipshod claims about Dr. Betensky's meta-analyses—and nothing else—for the remaining two.

2. Dr. Spector Admitted He Could Not Rule Out Alternative Explanations for the Data.

After failing to reliably apply the Bradford Hill criteria so that he could rule out "alternative explanations for the association," Ex. 19, *Reference Manual* at 598, Dr. Spector actually admitted that he could ***not*** rule out alternative explanations for the study results. *See Gopalratnam*, 877 F.3d at 779–80 (it is critical to "adequately account[] for obvious alternative explanations"). Dr. Spector did not contest the fact that the medical community agrees on a core alternative explanation for why some studies show higher rates of NEC with preterm formula: (1) "human milk is protective against NEC," with there being (2) "no conclusive evidence that preterm infant formula causes NEC." Ex. 1, Consensus Statement.[4] In fact, he admitted he did not know of anyone "who is not being paid by the plaintiffs' lawyers" "who has concluded that cow's milk formula causes NEC": "I do not." Ex. 7 at133:11–23.

[4] Many of the studies Dr. Spector relied on endorsed this consensus. *See, e.g.*, Ex. 3, Lucas & Cole, 336 The Lancet at 1522 ("breast milk may protect against necrotising enterocolitis"); Ex. 18, Adhisivam et al., *Does Fortification of Pasteurized Donor Human Milk Increase the Incidence of Necrotizing Enterocolitis Among Preterm Neonates?*, 32 J. Maternal-Fetal & Neonatal Med. 3232, 3234–35 (2019) ("Human milk provides the preterm neonates powerful immunological factors and enhances optimal intestinal colonization."). An expert relying on the studies of others must "not exceed the limitations the authors themselves place on their study." *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, 707 F. Supp. 3d at 336. *See also In re Onglyza Prods. Liab. Litig.*, 93 F.4th 339, 346 (6th Cir. 2024) (affirming exclusion of an expert who relied on studies that showed an association but "did not come to a conclusion about causation").

Dr. Spector drafted his report to disagree with the medical consensus, including by invoking Dr. Sucre to suggest there are ingredients in formula that might cause NEC. Ex. 8 at 25. He had to do this since general causation "examines whether ***the substance*** . . . had the capacity to cause the harm alleged," not whether the substance merely lacks some protective quality present in something else—particularly when that "something else" is naturally occurring and irreplicable, like mother's own milk is. *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015) (internal citations omitted and emphasis added); *see also* Ex. 19, *Reference Manual* at 598 ("Epidemiologists use causation to mean that an increase in the incidence of disease among the exposed subjects would not have occurred had they not been exposed to the agent.").

But he readily abandoned this causation claim at his deposition. He admitted that he could not identify anything in formula that causes NEC. Ex. 7 at 61:23–63:16. He then confessed that he could not reject the medical consensus that "what accounts for the difference in NEC rates between human milk and cow's milk formula is the absence of [protective] ingredients in human milk from cow's milk formula": "I believe that's a reasonable supposition." Ex. 7 at 65:14–20.

Ruling out alternative explanations for study findings is, as even Dr. Spector admits, "at the heart of epidemiology." Ex. 7 at 40:12–17; Ex. 20 at 31:22–25 ("Q. Is it critical to consider alternative explanations for a statistically significant finding like this? A. Yes."). Dr. Spector's confessed inability to rule out a protective effect of human milk as an explanation for his study findings is disqualifying. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013) (expert must "show why a particular alternative explanation is not, in the expert's view, the sole cause of the disease"); *DeLong Co., Inc. v. Syngenta AG*, 2024 WL 1343592, at *14 (W.D. Wis. Mar. 29, 2024) ("A failure to consider other factors may require exclusion of expert testimony when the omitted cause could have been the sole cause[.]"); *see also Gopalratnam*, 877 F.3d at

779–80; Ex. 19, *Reference Manual* at 605 (noting key causal factor of "Have Alternative Explanations Been Considered").

C. Dr. Spector's Opinions Bear Recognized Indicia of Unreliability.

The original *Daubert* decision "set forth a non-exclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony." Fed. R. Evid. 702 (2000 Ad. Comm. notes). Dr. Spector's methodology fails each of the five items on this checklist.

The first *Daubert* factor is "whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." *Id.* Dr. Spector admitted that several aspects of his methodology cannot be tested or because they consisted of untestable claims like finding consistency among studies by "eyeball[ing]" them, Ex. 7 at 235:7–9; 236:25 ("not easy to eyeball"), or discerning "emanations of a penumbra that suggest that there is a dose response" without any supporting quantitative data, *id.* at 301:21–25.

The second factor considers "whether the technique or theory has been subject to peer review and publication." Fed. R. Evid. 702 (2000 Ad. Comm. notes). Dr. Spector has not "subject[ed] [his claims] to peer review and publication," Ex. 7 at 197:9–11 ("I hadn't thought of it"), and as discussed above, would alter them if he did.

The third factor considers "the known or potential rate of error of the technique or theory when applied." Fed. R. Evid. 702 (2000 Ad. Comm. notes). Dr. Spector claimed that he could not identify the "error rate" in his systematic literature review in terms of the number of studies he missed. Ex. 20 at 118:5–11 (emphasis added). That alone fails the third factor. But the substance of his work actually established an alarmingly high error rate. After his first deposition, Dr. Spector produced a new and improper report containing analyses based on twelve clinical trials

that he had previously missed. These missed clinical trials nearly ***doubled*** the total clinical trials he ultimately reviewed, meaning that he had a remarkable error rate of nearly 50 percent. *Compare* Ex. 8 at 13–14 (listing 12 randomized control trials); Ex. 21, Suppl. Rep. at 7–8 (listing 12 previously missed randomized control trials). And he left his second deposition admitting that even that error rate was understated because there were yet more studies he should have considered but had failed to catch through a lack of diligence.[5] *E.g.*, Ex. 20 at 152:18 ("I would have included them"). Helpfully, Dr. Spector cited an article in his new report that quantifies how egregious his error rate was. Ex. 21 at 4 n.4. That study found that a method of reviewing studies that "misses about 13% of relevant studies" should "not be used for systematic reviews." Ex. 24, Gartlehner, *Single-Reviewer Abstract Screening Missed 13 Percent of Relevant Studies: A Crowd-Based, Randomized Controlled Trial*, 121 J. Clin. Epidemiology, 20, 27 (2020). Dr. Spector exceeded that unacceptable error rate several times over.

The fourth factor is "the existence and maintenance of standards and controls." Fed. R. Evid. 702 (2000 Ad. Comm. notes). Dr. Spector admitted that he abandoned portions of the PRISMA checklist standards he purported to apply. Ex. 7 at 220:9 ("I did not follow this approach to the T.").

Finally, the fifth factor considers "whether the technique or theory has been generally accepted in the scientific community." Fed. R. Evid. 702 (2000 Ad. Comm. notes). As noted above, Dr. Spector admitted that his views have no acceptance at all in the medical community.

[5] While Dr. Spector somewhat nonsensically claimed that he might not have included all these missed studies in his original report, he included them in his amended report and claimed that report was fully reliable. But even accepting his after-the-fact claims about some of what he missed being "irrelevant," he still admitted that he missed no less than 20% of the total relevant dataset. Ex. 20 at 48:24–49:7.

Ex. 7 at 133:21–134:1 ("Q. Do you know of anyone who [has concluded that cow's milk formula causes NEC] who is not being paid by the plaintiffs' lawyers? A. I do not[.]").

In addition to failing every *Daubert* factor, Dr. Spector failed the most basic methodological requirement of Rule 702 itself. Rule 702 requires that opinions be based on "sufficient facts or data" and that they involve a "reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. This, in turn, requires that a reliable methodology start from reliable data, *Caraker v. Sandoz Pharms. Corp.*, 172 F.Supp.2d 1046, 1048 (S.D. Ill. 2001), with "any step that renders the analysis unreliable ... render[ing] the expert's testimony inadmissible." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir.1994)).

Dr. Spector claimed his original report was reliable in spite of its errors and that he relied on it for his causation opinion. And after hemming and hawing, Dr. Spector eventually testified that his second report was also scientifically reliable, Ex. 20 at 22:14–18, and volunteered that he relied on *it* for his causation opinion, *id.,* at 23:2–4.

But Dr. Spector's new report relies on data he agreed was both "irrelevant" and "unreliable." Ex. 20 at 62:24–63:11. He nevertheless claimed that he could include this "irrelevant" and "unreliable" data in Dr. Betensky's meta-analyses, that the unreliable data does not render the analyses based on it unreliable, that those meta-analyses are in fact just as reliable as Dr. Betensky's other meta-analyses, and critically, that he was ***relying on them*** for his causation opinion. *Id.* at 63:21–64:1, 64:19–22.

Reliable data is a necessary condition for any reliable methodology and any expert opinion. Ex 19, *Reference Manual* at 588 ("If the researcher uses an unreliable source of data, the study may not be useful."); *ZF Meritor LLC v. Eaton Corp.*, 646 F.Supp.2d 663, 667–68 (D. Del. 2009)

(excluding expert because expert relied on unreliable data). Dr. Spector's willingness to deviate from this most basic requirement of Rule 702 renders his entire methodology unreliable and his opinions excludable.

II. Dr. Spector's Opinions Should Be Excluded Because They Do Not Fit the Facts of Any Case and Would Not Help the Jury.

Rule 702 requires a "rational connection"—a fit—between an expert's opinion and the facts of a case. *Gopalratnam*, 877 F.3d at 781; Fed R. Evid 702(a) (requiring expert to be "helpful" to trier of fact). An expert opinion not "tied to the facts of the case" cannot "aid the jury in resolving a factual dispute" and is therefore not helpful. *Deimer v. Cincinnati Sub-Zero Prods.*, 58 F.3d 341, 345 (7th Cir. 1995) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 591 (1993)). Therefore, an opinion given "with little to no evaluation of the actual facts of the case" is inadmissible. *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 75 (7th Cir. 2013). Dr. Spector's opinions are wholly inapplicable to the facts of the cases here.

Dr. Spector agrees that his causation opinion depends on "the percentage of [the infant's] diet that is made up of formula. Ex. 7 at 286:19–22. That is consistent with the legal requirement that causation experts show the level of exposure needed to cause harm. *See, e.g.*, *Krik*, 870 F.3d at 674–75 (affirming district court's rejection of an "any exposure" theory); *In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 946 (11th Cir. Oct. 18, 2024) (While "[a] plaintiff's exposure to the threshold dose of a toxin is relevant to specific causation," one must also ask "whether a harmful level of the toxin exists in the first place.").

But Dr. Spector did ***no analysis*** of NEC risk in "infants based on the percentage of formula they were fed." Ex. 7 at 393:17–20. Nor did he "conduct any analyses comparing [infants fed] exclusively human milk to babies fed a combination of human milk and cow's milk formula." *Id.* at 183:16–184:3, 254:6–8; *see also id.* at 347:13–17 (admitting that he "did not separate out"

studies in which formula was used as a supplement to human milk). And he has no idea what "threshold dose" of formula would even be necessary to cause NEC, if any. *Id.* at 184:23–25 ("There may be one, but I did not isolate it.").

It is no surprise, then, that when Dr. Spector was asked how much of the diet must be formula in order for it, in his opinion, to cause NEC, he confirmed that his opinion was limited to only those infants who received a diet of ***100% formula.***

> Q. What percentage is sufficient to cause NEC in terms of cow's milk formula?
>
> A. Not able to give you that number.
>
> Q. Is 50 percent sufficient?
>
> A. I'm not able to give you that number.
>
> Q. Is 75 percent sufficient?
>
> A. I'm not able to give you that number.
>
> Q. Is 90 percent sufficient?
>
> A. **When you get to 100 percent, I'll say it's sufficient.**
>
> Q. Okay. Is 99 percent sufficient?
>
> A. Not able to give you that number.

Id. at 286:23–287:9. He explained why he could not testify that anything less than a 100% preterm formula diet caused NEC: he did not conduct any analysis of that question.

> Q. Did you do any analysis of formula limited to formula as a supplement to maternal milk?
>
> A. I did not.

Id. at 254:6–8.

These failures render Dr. Spector's opinion wholly unhelpful in any case where the infant received less than 100% formula. And given the preference for human milk and the concerted efforts to help mothers produce their own milk, that is the vast majority of cases. *See, e.g.*, Ex. 11, Am. Academy of Pediatrics, *Necrotizing Enterocolitis Overview*, AAP.org (last updated July 17,

2024) (recognizing that mother's milk is "optimal nutrition source"); Ex. 4, AAP 2012 (discussing benefits of donor human milk).

Two of the bellwether cases illustrate this point. In *Etienne*, D.B. received a diet comprising ***more than 90% human milk*** before developing NEC. Ex. 12, Flanigan Rep. at 14. And in *Mar*, R.M.'s feedings contained about ***95% mother's own milk*** and only about 5% formula. Ex. 13, DeZure Dep. Tr. 12/13/2024 224:24–25 (agreeing that 95% was "a fair number"). Dr. Spector admitted he failed to do ***any*** analysis of cases like these, and accordingly conceded that he had no opinion about them:

> **Q.** You didn't do any analysis comparing infants, preterm infants fed a diet of 90 percent human milk and 10 percent bovine-derived product versus infants fed 100 percent human milk, correct?
>
> **A.** To the best of my knowledge, that's correct.
>
> * * *
>
> **Q.** Okay. So you're not going to offer an opinion saying when an infant gets 90 percent human milk, a 10 percent bovine product supplement to that diet will increase the risk of NEC by X percent, correct?
>
> **A.** Not based on the literature that we've talked about today.

Ex. 7 at 358:2–9; *id.* at 359:10–16. Dr. Spector is not even aware of a ***single study*** showing that the infants like those in *Mar* and *Etienne* are at any increased risk of NEC compared to infants who did not receive any formula. *Id.* at 349:18–350:2

These failures are fatal for his ability to offer helpful testimony in the myriad of cases in which hospitals follow guidance from the American Academy of Pediatrics ("AAP") and administer mother's milk, and then, when appropriate, donor milk, followed by preterm formula. *See Wintz By & Through Wintz v. Northrop Corp.*, 110 F.3d 508, 513 (7th Cir. 1997) ("[T]he

expert should offer an opinion as to whether the dose to which the plaintiff was exposed is sufficient to cause the disease.").

Dr. Spector then conceded a second, independently dispositive "fit" defect in his testimony. The scientific community recognizes, and Dr. Spector conceded, that NEC risk varies meaningfully by birth weight. Ex. 7 at 394:4–11.[6] But he limited his opinions to only infants with a birthweight of less than 1,500 grams and admitted that he could not give a causation opinion applicable to infants born weighing above 1,500 grams:

> **Q.** Do you know if the available studies show an increase in NEC rates with preterm formula versus human milk in infants with a birth weight of above 1,500 grams?
>
> **A.** I don't know specifically.
>
> * * *
>
> **Q.** Do your opinions apply to low birth weight babies [*i.e.*, those born between 1,500 and 2,500 grams]?
>
> **A.** . . . I could not give you a specific answer there.
>
> * * *
>
> Q. Do you know what the relative risk would be if you excluded studies that only looked at infants under 1,500 grams?
>
> A. I do not.

Id. at 108:10–14, 211:21–212:3, 155:12–15.

These admissions disqualify Dr. Spector from offering opinions in a host of other cases where the infants weigh above 1500 grams. Again, a bellwether case is illustrative. In *Diggs*, the infant was born weighing 2,095 grams. *See* Ex. 15, Flanigan *Diggs* Rep. at 5; *accord* Ex. 16, Smith Rep. at 12. For a case like *Diggs*, Dr. Spector cannot infer an association—much less causation—

[6] As an illustration of this point, the AAP recommends prioritizing human donor milk for babies below 1500 grams for precisely this reason. Ex. 5, AAP 2017 at 1, 3 (recognizing that "studies support health benefits for [donor milk's] use in infants with a birth weight <1500 g, ***especially in decreasing rates of necrotizing enterocolitis***.") (emphasis added).

between formula and NEC in infants weighing more than 1,500 grams. He simply "did not do that analysis" and does not "have any data that really addresses that" situation.

> **Q.** So is it possible for that subcategory of infants, those that are both above 32 weeks and above 2,000 grams, that there is no association between necrotizing enterocolitis and formula in that cohort? . . .
>
> **A.** I don't have any data that really addresses that.

Ex. 7 at 345:14–345:24 (objection omitted).

* * *

> **Q.** And you don't know one way or the other, for instance, what the relative risk rate would be between infant formula and infants born above 2,000 grams and above 32 weeks gestation because you did not do that analysis, fair?
>
> **…**
>
> **A.** There is a degree of extrapolation one can make, however, I did not do that analysis.

Id. at 394:19–395:11 (objection omitted).

Taken together, Dr. Spector's opinion applies only to infants who received 100% formula ***and*** who were born at less than 1,500 grams. To defendants' knowledge, ***no case*** in the MDL satisfies those criteria. Certainly, the four bellwether cases do not, as each of those infants received at least some human milk and at least one was born at more than 1,500 grams. *See supra*; *see also* Ex. 14, DeZure Rep. *Inman*, at 7–8 (listing feeding that included donor milk, mother's own milk, and formula). As a result, Dr. Spector's general causation opinion is irrelevant and unhelpful to the jury, and it should be excluded. *See Deimer*, 58 F.3d at 345.

III. Dr. Spector Is Not Qualified to Offer His Causation Opinion.

Although Dr. Spector holds a Ph.D. in epidemiology, he has no background knowledge in nutrition, the care of preterm infants, or NEC. Instead, he is an epidemiologist whose research focuses on childhood cancers. Ex. 7 at 315:12–21 (admitting that his work instead focuses on childhood cancer). The relevant question for Fed. R. Evid. 702 is not whether Dr. Spector "is

qualified in general, but whether his qualifications provide a foundation for him to answer [the] specific question" at issue here. *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010).

Dr. Spector is not a medical doctor. He has never evaluated any potential relationship between feeding and NEC. Ex. 7 at 24:12–14. His research "does not focus on fetal or neonatal nutrition." *Id.* at 114:25–115:1. He has never cared for a preterm infant with NEC. Indeed, he is "[a]bsolutely not" qualified to do so. *Id.* at 48:3–5. He has never been involved with making a recommendation about what to feed a preterm infant. *Id.* at 6–9. He would not be qualified to do that either. *Id.* at 10–14. Before being hired in these cases, Dr. Spector had never researched NEC, surveyed the science, or tried to determine the causes of NEC. Ex. 7 at 23:10–12, 23:16–19, 39:5–9. And while he initially claimed "to have studied [NEC] incidentally in other work," *id.* at 11:20–12:1, he later confirmed that this "incidental" study of NEC was irrelevant to his opinions: in one decade-old publication that had nothing to do with NEC, he had cited a single publication written by someone else that had the word "NEC" in its title. *Id.* at 310:19–25. Accordingly, his opinions were "developed expressly for purposes of testifying" rather than "growing naturally and directly out of research [the expert has] conducted independent of the litigation." *Gopalratnam*, 877 F.3d at 779–80.

But instead of taking steps to compensate for this lack of background knowledge before offering an opinion contrary to the medical community, Dr. Spector did nothing:

- He did not take the time to learn the literature. *E.g.*, Ex. 7 at 260:14–18 (admitting he spent 42.5 hours total on literature review); Ex. 17, Spector: Irrelevant Studies (listing thousands of studies "irrelevant" despite never reading or reviewing those studies).
- He ignored prior SLRs and meta-analyses even though his stated methodology required him to have considered those materials, and as a result missed dozens of studies. Ex. 7 at 25:23–26:1, 186:14–16, 231:6–14.
- He failed to account for or acknowledge the known fact that human milk protects against NEC. *Id.* at 74:6–10 ("I certainly saw some language to that regard, but I didn't quantitate it.")

- He did not even learn whether there was any difference between formula and fortifier—two products with totally different clinical uses. *Id.* at 168:5–9.
- He ignored all animal or *in vitro* data despite claiming he had considered this factor. *See id.* at 194:15–20.

Courts are appropriately wary when experts stray too far from their knowledge base. *Gayton*, 593 F.3d at 617 (affirming exclusion because, despite being a doctor, the expert "lack[ed] … specific knowledge of cardiology and pharmacology"); *Obrycka v. City of Chicago*, 2012 WL 4092653, at *4–*5 (N.D. Ill. Sept. 17, 2012) (St. Eve, J.) (excluding otherwise qualified statistician from offering an opinion because expert lacked any "professional, practical, or academic expertise in assessing police organizations and police culture"). This reasoning applies fully here.

As an epidemiologist who has no experience in NEC or preterm formula, and who made no meaningful effort to learn the science in this area, Dr. Spector is not qualified to give his causation opinion and should be excluded for this separate reason. Fed. R. Evid. 702.

CONCLUSION

For all the above reasons, the Court should exclude Dr. Spector's testimony.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon counsel of record on February 7, 2025, via the Court's electronic filing system and via email for any material provisionally filed under seal.

/s/ Emily S. Ullman